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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC., a Delaware corporation,

Plaintiff,

v.

SPD SWISS PRECISION DIAGNOSTICS GmbH, a Swiss Corporation,

Defendant.

Case No. 14-CV-585 (AJN) (GWG)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF SPD SWISS PRECISION DIAGNOSTICS, GMBH'S MOTION IN LIMINE TO DISMISS ALL FALSE ADVERTISING CLAIMS

The Hon. Alison J. Nathan

Trial Date: April 20, 2015

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INTRODUCTION

Plaintiff Church & Dwight Co., Inc.'s ("C&D") Lanham Act claim should be dismissed prior to trial. First, the claim challenges advertising that was expressly approved – indeed mandated – by the U.S. Food & Drug Administration (the "FDA") pursuant to its authority under the U.S. Food, Drug and Cosmetic Act (the "FDCA"). Second, C&D's theory is untethered to specific advertising and, instead, seeks to overturn the FDA's clearance of the Clearblue Advanced Pregnancy Test with Weeks Estimator (the "Week Estimator" or the "Product") for sale in the United States. The well-established doctrine of FDCA preclusion bars both theories.

Extensive correspondence between SPD Swiss Precision Diagnostics, GmbH ("SPD") and the FDA, which the Court was unable to consider on SPD's motion to dismiss, shows that the FDA controlled every element of SPD's packaging and directed the messaging on other promotional materials. Now that discovery is complete and the Court is no longer subject to the procedural constraints of Federal Rule of Civil Procedure 12(b)(6), the record establishes that C&D's challenge directly conflicts with the FDA's conclusion that SPD's marketing materials will not mislead consumers.

Additionally, discovery has revealed that C&D's theory is not confined to the notion that certain advertising for the Product is false or misleading: C&D is attacking ***the Product itself*** as inherently misleading and unsafe. In other words, C&D is asking this Court to reverse the FDA clearance because, according to C&D, the Product is providing inherently misleading information to consumers. Again, this violates the FDCA's clear delegation of exclusive authority to the FDA to determine whether a medical device such as the Weeks Estimator may be sold in the United States.

The Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), decided after this Court ruled on SPD's motion to dismiss, reaffirmed the principle that

Lanham Act claims directly conflicting with specific FDA judgments – in particular pre-approvals of labeling – are barred. A Lanham Act claim constituting a direct assault on the FDA's exercise of its authority under the FDCA, which is precisely what C&D is attempting here, is the type of claim that courts continue to bar even after *Pom Wonderful*.

PROCEDURAL HISTORY

C&D's complaint, filed in January 2014, challenged the advertising for the Weeks Estimator as unlawful because the advertising allegedly violated marketing restrictions imposed by the FDA. (Dkts. 2 and 93 at 17.) On February 11, 2014, C&D filed a motion for a preliminary injunction on the same theory. (Dkt. 20.)

In opposing the preliminary injunction application, SPD proffered detailed evidence, including extensive correspondence between the FDA and SPD leading up to clearance of the Product, showing that the FDA invoked special statutory authority to control SPD's packaging and marketing materials and, after exhaustive review, ultimately approved it. (Dkt. 86.) This review and approval process included imposition of mandatory disclosures the FDA considered adequate to address risks that are a centerpiece of C&D's claims. SPD urged the Court to deny C&D's motion under the doctrine of FDCA preclusion: when a Lanham Act claim invites a court to usurp the authority of the FDA under the FDCA, the claim is barred.

SPD contemporaneously moved to dismiss the complaint under Rule12(b)(6) on the same ground. (Dtk. 59.) SPD requested judicial notice of much of the correspondence submitted in opposition to the preliminary injunction. (Dkt. 60.)

At the initial pretrial conference on April 4, 2014, the Court proposed to address first the FDA issue raised in both the preliminary injunction papers and the motion to dismiss, followed quickly – if necessary – by a trial on the merits. (Dkt. 42.) C&D repeatedly resisted that proposal, making clear it sought to avoid the Court's early consideration of the FDA

correspondence extrinsic to the complaint. (Knowles Decl., ¶ 8, Ex. G, p.1.)

Oral argument on both motions was held on May 22, 2014. (Dkt. 94.) There, C&D took the position that the preliminary injunction motion was no longer at issue (and thus the Court should not consider the extrinsic evidence submitted in opposition to that motion). (*See* Dkt. 93 ["MTD Order"] at 30.) C&D also vigorously opposed SPD's request for judicial notice.

On June 3, 2014, the Court issued its opinion and order on the two motions, denying the motion to dismiss and declining to reach the arguments raised in the preliminary injunction briefing. (MTD Order.) The Court's decision not to reach the FDA issue in the context of the preliminary injunction motion was based, in part, on the pendency of the *Pom Wonderful* decision and, in part, on C&D's effective withdrawal of that motion at the hearing. (MTD Order at 30.) Pursuant to Rule 12(b)(6), the Court declined to take judicial notice of the FDA record submitted by SPD, and so did not consider that information in deciding the motion to dismiss.

Based on the limited record of C&D's allegations, the Court was not able to conclude that the cases barring Lanham Act claims due to an "actual conflict" with FDA decision-making were dispositive. The Court explained that "the regulatory scheme governing the Weeks Estimator does not – ***in itself*** – provide a basis to conclude that he Weeks Estimator box, label or advertising has been authorized by the FDA."[1] [MTD Order at 21-22.] Similarly, "viewed in the light most favorable to C&D, the Clearance Letter – ***standing alone*** – does not demonstrate that the FDA has reviewed the Weeks Estimator box and labeling actually sold by SPD and determined it will not mislead consumers as to the capabilities of the Weeks Estimator." (Order at 23.) The Court concluded by stating:

> In sum, and recognizing that this is a doctrine that does not lend

[1] Unless otherwise indicated, all emphasis is added.

> itself to a simple application, the Court concludes that the ***materials before the Court*** do not, ***as this time***, warrant preclusion of C&D's claims. The Court notes, however, that the questions raised by this doctrine are often fact-intensive, and are frequently resolved after the pleadings stage. As a result, ***it may be that SPD is able to re-raise this argument at a later stage, if appropriate given the development of the proceedings***.

(MTD Order at 25 (citations omitted).)

FACTUAL BACKGROUND

I. The Weeks Estimator Product

The Weeks Estimator is a unique, scientifically advanced, and well-established product. It has been launched in nearly 30 countries since July 2008 when it was first put on the market in the UK and Ireland. (Dtk. 90 [Declaration of Mark Gittins ("Gittins Decl.")], ¶ 7.) The Weeks Estimator differs from other home pregnancy tests in that, in addition to indicating whether or not a woman is pregnant, a woman who obtains a "pregnant" result will receive an estimate of how many weeks have passed since she ovulated (when an egg was released from her ovary). As fertilization occurs less than 24 hours of ovulation, the estimate of weeks since ovulation provides an estimate of when pregnancy started. The test's estimate is based on the level of human chorionic gonadotropin ("hCG"), sometimes called the "pregnancy hormone," in a woman's urine. Levels of urinary hCG rise very quickly in early pregnancy, and reach predictable levels at various stages. The test measures the hCG in the pregnant woman's urine, and depending on the level, digitally displays a result in the product window. When the result is positive, the display reads "Pregnant" and, below that, estimates weeks: "1-2," "2-3," or "3+" weeks. (Gittins Decl., ¶¶8-13.)

II. The Weeks Estimator Is A Medical Device Regulated By The FDA.

The FDCA, as amended by the Medical Devices Amendments of 1976, separates medical devices into three categories for purposes of the level of regulatory scrutiny they receive. "Class

I" devices present "no unreasonable risk of illness or injury" and therefore are subject to minimal regulation. "Class II" devices present greater potential risk of harm and are therefore subject to somewhat greater regulatory scrutiny. *See generally*, 21 U.S.C. § 360c(a), *et seq*.

Home pregnancy tests, such as the Weeks Estimator, are considered Class II medical devices. (Gittins Decl., ¶ 21.) The FDA does not permit a new home pregnancy test to be marketed unless the manufacturer has received clearance by the agency for the product to be marketed for a particular "intended use." (*Id.* at ¶ 18.) The review process for a new home pregnancy test product is commenced by the filing of a "premarket notification" submission to the FDA (known as a 510(k) application). 21 C.F.R. § 807.81. The 510(k) application provides a description of the new device, and a description of the intended use of the product, including "a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended." 21 C.F.R. § 807.92.

The 510(k) application is intended to demonstrate to the FDA that the device is at least as safe and effective as – i.e., "substantially equivalent" or "SE" to – a legally marketed predicate device. 21 C.F.R. § 807.92. Before marketing a Class II device, the submitter must receive a letter from the FDA that finds it to be substantially equivalent, and states that the device can now be marketed in the US. This "clears" the device for commercial distribution, and so is generally referred to as a "clearance letter" or "SE letter." (Gittins Decl., ¶ 19.) On December 10, 2012, SPD received a clearance letter following submission of a 510(k) for the Weeks Estimator. (Gittins Decl, ¶ 37, Ex. K [the FDA's December 10, 2012 Clearance Letter (the "Clearance Letter")].)

III. The FDA Applied Enhanced Scrutiny To The Product Labeling Due To Its Finding Of A Risk Of Off-Label Use By Consumers.

In the course of the FDA's review of the Product, the FDA's Office of In Vitro

Diagnostics and Radiological Health ("OIVD") identified a concern about the Weeks Estimator feature of the Product: that women could misinterpret its results and/or use the Product for unintended purposes, with potentially adverse health consequences. (*See* Clearance Letter, p.1.) It therefore invoked Section 513(i)(1)(E) of the FDCA, a statutory procedure under which the FDA evaluates a new Class II medical device with heightened scrutiny and imposes marketing limitations to address any identified risks of harm. Any resulting clearance is known as an "SE (substantial equivalence) with limitations." (Gittins Decl. ¶¶ 23-26 & Ex. B.)

When section 513(i)(1)(E) is invoked, the Director of the FDA division primarily responsible for the clearance of the product (in this case the Director of OIVD) has additional power – and the obligation – to control the labeling and other advertising for the product for the purpose of avoiding the identified risks.[2] 21 U.S.C. §360c(i)(1)(E).

Here, the FDA invoked Section 513(i)(1)(E) in what is known as a "hold letter." (Gittins Decl., ¶ 22, Ex. A [the "Hold Letter"].) The September 12, 2012 Hold Letter notified SPD that the FDA would place the 510(k) submission for the Weeks Estimator on hold pending receipt of certain additional information, and directed SPD to submit updated proposed labeling containing a revised "Indications for Use" ("IFU") statement. (*Id.*)

The Hold Letter specified the FDA's concerns, which paralleled the risks later asserted in C&D's Complaint. (*Id.*) The FDA noted that the Weeks Estimator result "is not aligned with gestational aging done by healthcare professionals (i.e., it will under-estimate gestational age by an average of 2 weeks)." (*Id.*) In particular, the FDA's concern was that users may:

> misinterpret weeks results to be a substitution for gestational age

[2]The term "labeling" under the FDCA means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

> determination or may misinterpret weeks results to mean they are pregnant and their pregnancy is progressing in a healthy manner (e.g., because they are moving from 1-2 weeks to 2-3 weeks to 3+ weeks according to device results). These misinterpretations may cause the user to delay or forego necessary care by a healthcare professional. For example, uses may not recognize symptoms of ectopic pregnancy because of improper assumptions based on this device output and may not seek appropriate medical care.

(*Id.*) The FDA was clear about how its concerns over harm from user misinterpretation of the Weeks Estimator results should be resolved: it concluded that "[d]elay in appropriate care in these situations is a harmful health impact ***that may be prevented given adequate device labeling.***" (*Id.*; Gittins Decl. ¶ 23.) If the FDA had ***not*** determined that the risks could be prevented with labeling, it would not have been permitted to clear the product, even "with limitations." 21 U.S.C. §360c(i)(1)(E)(ii)(III).

IV. The FDA Controlled The Labeling And Marketing Of the Weeks Estimator In Order To Avoid The Risks Forming The Basis For C&D's Claims.

After invoking the SE with limitations process, the FDA and SPD engaged in weeks of detailed dialogue about the limitations and disclosures to be required for the Weeks Estimator. (Gittins Decl., ¶¶ 28-37, Exs. C-K.) The review was comprehensive. In the Hold Letter itself, the FDA communicated the following to SPD about the box labeling alone:

- "The front panel of your box labeling states 'Also Tells you How Far Along you Are.' ***Please remove this statement from every area of your box labeling***."
- "You have provided some information regarding the accuracy of your 'Results 5 Days Sooner' claim, but this information is in small font towards the bottom portions of your box labeling and is difficult to read. ***Please more prominently place this information on your outer box labeling***."
- "***Please remove the '99% accurate for pregnant or not pregnant result' statements from your box labeling***. This statement is misleading as it does not capture the accuracy of the entire test (including the weeks estimator feature which is significantly lower). Accuracy of the pregnant or not pregnant result should also be removed from your package insert."
- "We have noticed that a statement describing the minimum accuracy of the weeks estimation indicator has been added to your box labeling. ***Please remove this information from your box labeling***. Accuracy of the weeks estimation

indicator may be included in the package insert."

- "You have included (4) steps on your box labeling:

    1. Easy
    2. Accurate
    3. Clear
    4. Tells you how far along you are

    Please remove these steps from your box labeling and instead add a statement referring the user to the package insert for test instructions and for more information on the weeks [estimator] feature."

(Hold Letter.)

The Hold Letter also mandated that the packaging (inside and out), as well as all "promotional materials," contain an FDA-crafted "Indications for Use" statement ("IFU") that explained to consumers that the Product provides an estimate different from the one a doctor might provide. The IFU provides additional information as well, all of which is aimed at avoiding consumer confusion about the Product results or how the Product should be used. (Gittins Decl., ¶ 30, Ex. D.)

Over the course of the next several months, the FDA controlled everything from font size to where certain language should be placed on the box and on the package insert. (*See, e.g.*, Gittins Decl., ¶ 30, Ex. D ("We found it difficult to read blue font on a blue background and consumers may find this difficult as well.").) The FDA review even controlled the name of the Product. The Hold Letter directed that the new name should include the phrase "Weeks Estimation Indicator." On October 2, 2012, SPD submitted responses to various FDA requirements and requested leave to replace "Weeks Estimation Indicator" with "Weeks Estimator." The FDA responded to SPD's proposed labeling on October 18, 2012, accepting SPD's suggestion regarding the product name, but not other proposed changes. (Gittins Decl, ¶¶ 29-30.) This extensive process not only makes clear that the FDA comprehensively controlled the Product packaging, but that it did so with the express intent to ensure that it would not mislead consumers with respect to the Weeks Estimator function of the Product. (Hold Letter;

see Gittins Decl., ¶¶ 28-37, Exs. C-K.)

On November 20, 2012, SPD sent a final version of proposed labeling to the FDA. (*Id.* at ¶ 33, Ex. G.) On November 27, 2012, the FDA sent an approval email to SPD stating that the labeling "appears to meet our requests." (*Id.* at ¶ 34, Exh. I.) On December 10, 2012, the FDA issued its Clearance Letter, an SE With Limitations, clearing SPD to begin marketing the Weeks Estimator. The Clearance Letter included a series of limitations on the Product's box and the package insert (as well as other marketing materials) that were the result of the months-long scrutiny of the label. (Clearance Letter, pp.1, 3.)

V. The FDA's Post-Launch Control of Week Estimator Advertising.

On October 10, 2013, C&D wrote to the FDA asking it to take "corrective action" against SPD for having purportedly "violate[d] the labeling restrictions imposed in the Clearance Letter." (Declaration of Jeffery Knowles ["Knowles Decl."], ¶ 2, Ex. A.) In that letter brief and a second one on November 1, 2013, C&D attacked the same advertising it attacks here, on the same theory. (Knowles Decl., ¶ 3, Ex. B at CD0000002, CD0000004, Ex. B at CD0000037 & CD0000038.)

The FDA investigated C&D's allegations, notifying SPD in November 2013 of its intention to evaluate SPD's advertising, thus beginning the post-launch discussions detailed below. (Gittins Decl., ¶ 43, Exh. M.) Although the FDA had authority to order SPD to stop marketing the Product, to impose monetary penalties or simply to find officially that the challenged advertising was misleading, it did none of those things. (Gittins Decl., ¶ 53.)

FDA's first step was to arrange a teleconference "to communicate our concerns and receive further clarifications." (Gittins Decl., ¶ 43, Ex. M.) Not surprisingly, given the origin of the inquiry, the concerns the FDA expressed paralleled certain aspects of the challenges C&D advances in its complaint. (*Id.*) With respect to the Product carton, the FDA expressed concern

about the insertion of the word "weeks" in the depicted display window and required that it be removed and replaced with the words "weeks along" outside the window – emphasizing that it had approved the latter phrase in the clearance process. (*Id.* at ¶ 47, Ex. O, Attch. 1.) Notably, the stated basis of the FDA's concern about the use of the word "weeks" inside the display window was not that it conveyed a false message about the estimate but that the Product window itself does not literally display the word "weeks" when it returns a positive result. That is, the readout on the package did not accurately reflect the form of readout on the test sticks. (*Id.* at p.3 of 4.)

On November 22, 2013, SPD submitted an overall mitigation plan and drafts of packaging that removed the word "weeks" from the display windows and replaced it with the words "weeks along" beneath the display windows as originally approved by the FDA. (*Id.* at ¶ 54, Ex. O, Attch. 2.) Except to request a revision to the font size of the phrase "weeks along," and to request an asterisk directing consumers to the IFU on the side of the pack, the FDA approved the packaging. (*Id.* at ¶ 56, Ex. Q.) The packaging approved by the FDA after the product launched is the same packaging currently in use.[3] C&D is challenging the current carton as false and misleading advertising as well. (Dkt. 140, p.23.)

The FDA also approved a video advertisement substantially similar to the Weeks Estimator television commercial challenged by C&D. In December 2013, SPD submitted a storyboard for an internet only version of the television commercial for FDA's review. (Gittins Decl., ¶ 65, Ex. V.) The FDA approved the new commercial for internet use with only minor changes. (*Id.* at ¶ 66, Ex. W.)

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[3] Notably, SPD offered to add a banner to each of the main panel's prominently displaying the claim "Only Test To Estimate Weeks Since Ovulation." The FDA approved this banner claim. (Gittins Decl., ¶ 54.)

ARGUMENT

I. Legal Standard.

The Court has inherent power to grant a motion in limine to preclude evidence or dismiss claims, where preclusion or dismissal will serve to narrow the issues necessary to be tried. *Luce v. United States*, 469 U.S. 38, 41, 105 (1984); *Lovejoy-Wilson v. Noco Motor Fuels, Inc.*, 242 F. Supp. 2d 236, 244 (W.D.N.Y. 2003) (considering evidence outside of the pleadings in ruling on an *in limine* motion); *Wright v. Kelly*, No. 95-CV-0688H, 1998 WL 912026, at *2 (W.D.N.Y. Oct. 16, 1998) (granting motion in limine to dismiss claims that were not legally cognizable); *United States v. Tokash*, 282 F.3d 962, 968 (7th Cir. 2002).

II. C&D's False Advertising Claims Are Precluded Because They Challenge Advertising Expressly Approved By The FDA.

A. The Law Bars Lanham Act Claims That Directly Conflict With The FDA's Exercise Of Its Statutory Authority.

In the course of extensively considering the body of law addressed to the doctrine of FDCA preclusion, the Court's MTD Order succinctly articulated the essence of the concept: "courts refuse to usurp the FDA's role in the enforcement of the FDCA and the FDA's authority under that statute." (*See* MTD Order at 14.) While the Court correctly observed that the cases present "an array of diverse fact patterns," the clearest examples of when preclusion must apply are when the claim being asserted directly conflicts with a fact-specific approval granted by the FDA in the exercise of its exclusive authority under the FDCA.

This Court has precluded claims on just this ground more than once. For example, in *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y 1987), McNeilab, the maker of Tylenol, claimed that American Home Products, the maker of Anacin and Advil, engaged in false advertising under the Lanham Act. The FDA had mandated that the packaging for Anacin contain a warning concerning the serious and even fatal risks of Reye

Syndrome from giving Anacin to children and teenagers to treat symptoms of influenza and chicken pox. *Id.* The labeling on packaging for Anacin, however, contained the word "SAFE" in prominent letters on the front of the package with the FDA-required warning regarding the risks of Reye Syndrome relegated to the "fine print" on the back. Granting American Home Products' motion for summary judgment, the court explained:

> It is true that the [Reye Syndrome] warning is buried in the fine print on the back of the Anacin package, while the front bears in large block letters the legend "SAFE, FAST PAIN RELIEF." This obviously creates the possibility that Anacin could be administered to a child or teenager with flu or chicken pox by a parent who perceived only a message of safety without being alerted to the danger, or taken by such a youngster on his or her own initiative without any suspicion of hazard. ***The consequences of such a mistake may be serious or even fatal. But this is a problem to be addressed by the FDA and not by the courts in a Lanham Act suit.*** Indeed, it is a problem which the FDA has already addressed, when it specifically approved the Anacin label in its entirety.

American Home, 672 F. Supp. at 145 (all emphasis added).[4]

The teaching of *American Home Products* is that a competitor is precluded from challenging the sufficiency of a product's label and marketing claims when the FDA has already approved those claims fully cognizant the risk of potential harm resulting from consumer misunderstanding about the label warnings and performance of the product.[5]

A second example is *Cytyc Corp. v. Neuromedical Systems, Inc.*, 12 F. Supp. 2d 296

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[4] C&D may argue that some these cases are inapposite because they involve pharmaceuticals, over which FDA *usually* has more power to regulate specific advertising language than over medical devices. But in this case, FDA was issuing an SE with limitations, which, pursuant to 21 U.S.C. §360c(i)(1)(E), gives FDA not just the right but the *obligation* to dictate advertising language protective of consumers. These cases are therefore directly on point.

[5] *See also SmithKline Beecham v Johnson & Johnson*, 1996 U.S. Dist. LEXIS 7257, *21 n.10, *41 (S.D.N.Y May 26, 1996) (court suggested that it would not substitute its "discretion for that of the FDA in approving package labeling for over-the-counter medications" by second-guessing the accuracy of those labels).

(S.D.N.Y. 1998). There, the plaintiff claimed that various statements made by Cytyc Corporation about an alternative cervical cancer detection system it manufactured and marketed called ThinPrep were factually false or misleading under the Lanham Act. This Court dismissed the claims under Rule 12(b)(6) finding that "[m]any of Cytyc's statements that NSI's claims are false or misleading are, in fact, consistent with the substantive claims approved by the FDA." *Id.* at 301. The Court held that because the challenged statements had been approved by the FDA, they were "non-actionable." The Court went on the conclude that even though some of the "statements do not correspond precisely to statements that the FDA has approved, the challenged statements . . . are similar enough to the approved statements for the Court to conclude, as a matter of law, that they are neither false nor misleading." *Id.* In sum, the Court held that "[w]hatever the merits of NSI's contentions regarding purported deficiencies in the testing and development of ThinPrep, representations by Cytyc that comport substantively with statements approved as accurate by the FDA cannot supply the basis for NSI's claims." *Id.*

In the MTD Order, the Court acknowledged this line of "actual conflict" cases, but concluded they did not control at the pleading stage of proceedings because:

> [N]o such conflict is apparent ***from the current record***. Specifically, viewed in the light most favorable to C&D, the Clearance Letter – ***standing alone*** – does not demonstrate that the FDA has reviewed the Weeks Estimator box and labeling actually sold by SPD and determined it will not mislead consumers as to the capabilities of the Weeks Estimator . . . . In short, the Court simply cannot determine, ***at this stage***, the precise nature of any conclusions the FDA may have made as to the Weeks Estimator.

(MTD Order, p.23.)

Now, of course, the Court may consider a full record, including the detailed correspondence leading up to the Clearance Letter. The exhaustive review process under Section 513(i)(1)(E) shows not only that the FDA controlled every element of the Product packaging, but that it did so with the express intent to ensure that consumer would not be misled about the

Weeks Estimator results. (*See, e.g.*, Hold Letter ("We have concerns that users misinterpret the weeks results to be a substitution for gestational age determination or may misinterpret weeks results to mean they are pregnant and their pregnancy is progressing in a healthy manner…… Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Indications for Use and in your device's labeling if your device is cleared.").) As a matter of law, those steps necessarily mean that FDA concluded that these marketing requirements were sufficient to prevent consumers from being confused and thereby harmed. 21 U.S.C. §360c(i)(1)(E)(ii)(III).

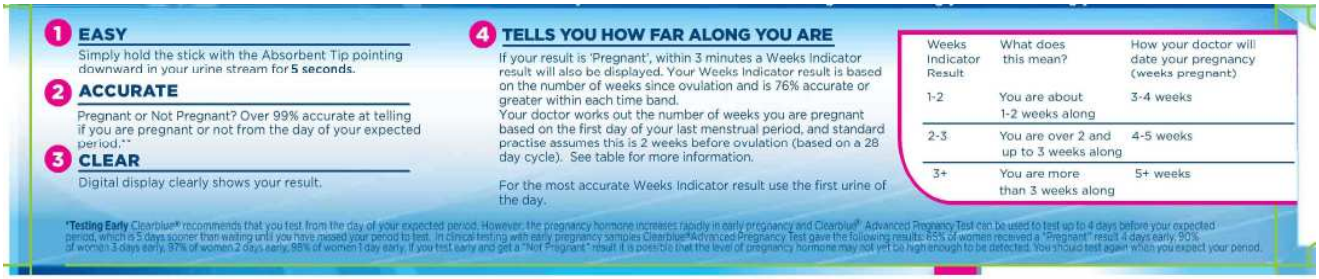
C&D will no doubt argue, as it has in the past, that the FDA's initial approval of the packaging should be disregarded due to small deviations in the packaging actually launched from the final version submitted to the FDA. But subsequent events debunk this contention. As noted, there were two small changes in the launch packaging relative to the final iteration provided to the FDA: (a) four readout window instead of two; and (b) replacement of the words "weeks along" just outside the windows with "weeks" inside the windows.

When the FDA approached C&D in November 2013, it objected to placement of the word "weeks" in the windows. As explained, however, this was not because it misled consumers about what the estimate means, but because the Product readout itself does not contain such a word. Ultimately, the FDA approved the use of all four windows, required removal of "weeks" from the "Pregnant" windows and directed SPD to replace the words "weeks along" immediately above these windows. Clearly, there is no reason to believe that the message communicated by "weeks along" adjacent to the readout window is materially different from the presence of the word "weeks" inside the readout window. Certainly C&D has made no attempt to show that the difference between the launch packaging and the approved packaging has any impact whatsoever on consumer perception of the Weeks Estimator's capabilities. Under these circumstances,

C&D's challenge to the launch package and the current package are barred. *See Cytyc*, 12 F. Supp. 2d at 301 (statements that did not "correspond ***precisely*** to statements that the FDA has approved" were still non-actionable where they were "similar enough to the approved statements") .

In its MTD Order, the Court acknowledged that "the potential for conflict between the FDA's views and a hypothetical judgment for C&D in this case exists, particularly given the Clearance Letter's directive that 'performance of the Weeks Estimator should not be displayed on your box labeling,'" but the Court noted that "this statement is ambiguous." The Court observed that this directive "could mean many things including a directive that SPD remove specific product claims that it had made in the proposed labeling." (MTD Order, p.24.)

Now that the full record is available, any ambiguity about this directive is removed. On August 13, 2012, SPD submitted to the FDA a proposed carton for the Weeks Estimator that had the following side panel:



(Declaration of Sarah Johnson ["Johnson Decl."], ¶¶ 3-4, Exs. A & B.) Thus, SPD proposed to include information about the "performance" of the weeks estimator feature on the outside of the box.[6]

[6] In addition to the Clearance Letter itself, which sets forth a table by which "Weeks Estimator performance" is to be presented, subsequent correspondence confirms that the FDA's references to the "performance" of the Product refer to the comparison of the Weeks Estimator's results with the estimates based on LMP. For example, on November 13, 2012, SPD proposed to include a row in that table showing the level of agreement between the Weeks Estimator results and the (footnote continued)

In the Hold Letter a few weeks later, the FDA observed that this panel included accuracy information for the weeks estimator feature and directed SPD to "remove this information from your box labeling. . . . Accuracy of the weeks estimation indicator may be included in the package insert." (Hold Letter) SPD understood the FDA to be requiring removal of all of the side panel information on Product performance, because claims about what the estimate means without stating accuracy levels could mislead consumers into believing the Weeks Estimator feature is 100% accurate. (Johnson Decl., ¶ 6.) SPD resubmitted the proposed carton to the FDA and informed the FDA that the information had been deleted. (Gittins Decl., Ex. C at 3, 10-11.) After the FDA reviewed several more iterations of the label, during which it addressed how Product "performance" should be described and displayed in the insert, the FDA included among its label "limitations" the requirement that "Performance of the Weeks Estimator should not be displayed on your box labeling." (Clearance Letter, p.1.)

In short, after SPD proposed to place information about the relationship between the Product estimate and a doctor's estimate on the outside of the package, the FDA ***forbid*** such placement. For C&D to contend now that this mandate is misleading to consumer is to attack the FDA's explicit exercise of its judgment under the FDCA.

In the MTD Order, the Court also observed that "it may be that the box – even if approved by the FDA when taken in conjunction with the package insert – is misleading to the consumer at the time of purchase due to the unavailability of the package insert at that time." (MTD Order, at 24.) In addition to the fact that the FDA mandated what information would go

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time of ovulation based on established methods. (*See* Gittins Decl., Ex. G at 1.) The FDA responded: "We do not agree with your proposal to include a 'How the Weeks Estimator agrees with time since ovulation' row to the Weeks Estimator performance table in your labeling." (*Id.*) The FDA directed SPD to remove that row, which SPD did. (*Id.*)

on the outside of the box and what information would go inside, the record is ***devoid*** of evidence suggesting that consumers' buying decision is in any way influenced by the placement of some information on the inside of the package rather than the outside. While C&D has speculated several times about whether this could cause consumers to be misled – and there are methods well known to C&D and to its experts to determine whether that speculation has any basis in fact – C&D made no effort whatsoever to make such a showing.[7] This simply cannot be a reason to overturn the FDA's considered determinations on this subject.

In short, on the full record, all doubt about the level of FDA control over the Weeks Estimator marketing has been eliminated. That involvement was so extensive as to constitute full control of the packaging even before its release. The involvement continued after launch, when the FDA evaluated C&D's allegations**.** Rather than draw the conclusions C&D is now asking this Court to draw – that the Product packaging, even after the small changes required by the FDA, continues to mislead consumers – the FDA reached the opposite conclusion: that the packaging is ***not*** likely to mislead consumers and thereby put them at risk.

C&D's claims are a naked attempt to challenge the FDA's determination that the Weeks Estimator product labeling is not misleading. Just as it did in *American Home Products*, the Court should reject this effort. *American Home*, 672 F. Supp. at 145(claim barred on preclusion grounds because the FDA had pre-approved the Anacin label fully cognizant of the specific risks of consumer confusion raised in McNeil's claims). A clearer case of "actual conflict" with a

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[7] This failure of proof also addresses the Court's footnoted observation that the difference between interior and exterior disclosures highlights the differing purposes of the FDCA and the Lanham Act: preservation of consumer safety vs. promotion of fair competition. That is, if there is no evidence that buyers are influenced whether to purchase the Product by the presence or absence of certain information on the outside of the package, this is not a factor bearing on competition.

specific FDA judgment, exercised pursuant to express FDCA authority, is difficult to imagine.

B. The Supreme Court Decision In *Pom Wonderful* Reaffirmed Preclusion Of Lanham Act Claims That Directly Conflict With FDA Action.

The Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), which this Court anticipated may provide guidance here, did nothing to erode the "actual conflict" line of cases. To the contrary, the decision lends additional support to the long-standing proposition that a Lanham Act claim that directly undermines the FDA's exercise of its statutory authority is precluded.

At the threshold, it is important to recognize that the issue the Court addressed in *Pom Wonderful* did not involve a claim in direct conflict with FDA review and approval of specific labeling. Rather it was concerned with the effect of general regulations: "This Court granted certiorari to consider whether a private party may bring a Lanham Act claim challenging a food label that is regulated by the FDCA." *Id.* at 2236 The Court held that the FDCA does not preclude a Lanham Act claim challenging the truth of food and beverage labeling merely because the FDA has promulgated regulations that touch upon such labeling. *Id.* at 2241.

Here, of course, SPD is not contending that C&D's claims are barred merely because the FDA regulates medical devices such as the Weeks Estimator. To the contrary, SPD's position rests on the FDA's exhaustive ***review and advance approval of the specific labeling*** for the Weeks Estimator product, under explicit statutory authority, a process that included mandatory disclosures and other detailed limitations on marketing that C&D's action would necessarily overturn.

The *Pom Wonderful* Court opinion emphasizes that it was not facing such a case:

> Unlike other types of labels regulated by the FDA, such as drug labels, see 21 U.S.C. § 355(d), ***it would appear the FDA does not preapprove food and beverage labels*** under its regulations and instead relies on enforcement actions, warning letters, and other measures.

Id. at 2239 (citations omitted)

Cases subsequent to the Supreme Court's decision in *Pom Wonderful* have recognized it did not do away with the doctrine of FDCA preclusion. *See JHP Pharm., LLC v. Hospira, Inc.*, No. CV 13-07460 DDP JEMX, 2014 WL 4988016, at *10 (C.D. Cal. Oct. 7, 2014) (passage quoted above "suggests that, at a minimum, the Court might find a Lanham Act claim precluded by the FDCA where it turns on the content of a drug label, especially if that drug lable were pre-approved by the FDA"); *Catheter Connections, Inc. v. Ivera Med. Corp.*, No. 2:14-CV-70-TC, 2014 WL 3536573, at *5 (D. Utah July 17, 2014) (distinguishing *Pom Wonderful* in precluding claim for false advertising on the ground that the challenged medical device required 510(k) clearance).

With respect to the Court's rationale that preclusion based on general regulation alone could cause "the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than in competitive markets for other products," *id.* at 2239, this case is an excellent example of where such a concern does not exist. Here, not only did the FDA invoke a special statutory procedure empowering and obligating the agency to review and pre-approve the specific labeling at issue (a duty it then discharged very thoroughly), the FDA ***again*** invoked that authority ***after clearance*** to enforce the limitations it imposed prior to clearance.

No doubt C&D will point to the passage of the *Pom Wonderful* opinion where the Court addressed the Government's contention that preclusion should apply when FDA regulations "specifically requir[ed] or authoriz[ed]" certain elements of the labeling – such as the name of the product. But the reasons given by the Court for rejecting this argument are inapplicable here. First, the Court expressed "practical concerns about drawing a distinction between regulations that 'specifically authorize' a course of conduct and those that that merely tolerate that course . . . ." Here, no such concern exists: this case does not center on a regulation of general application

but on the FDA approval of ***the specific labeling*** for ***this Product***. Moreover, it could not be clearer from the correspondence that FDA controlled ***every element*** of the Product packaging. There is simply no doubt that this label was not only specifically authorized; the FDA ***mandated*** disclosures and limitations in all respects material to this lawsuit.

This also distinguishes the second basis for the *Pom Wonderful* Court's rejection of the Government's position: the Government's assumption that the FDCA and its regulations are "a ceiling on the regulation of food and beverage labeling." *Id.* at 2232. In addition to observing that the Lanham Act and the FDCA were intended to "complement each other with respect to food and beverage labeling," the Court emphasized that "the FDA explicitly encouraged manufacturers to include material on their labels that is not required by the regulations." *Id.* at 2240. That is, the record reflected that the FDA itself did not consider its regulations a "ceiling."

Here, the opposite is true. The approval process itself made clear that the FDA would accept no material deviation from the packaging that it pre-approved. Indeed, within a week of receiving the Hold Letter, SPD inquired about the process. In response to SPD's inquiry about whether it would have input on labeling limitations, the FDA said "[c]omments will be considered; however ***FDA makes final determinations of labeling requirements for SE with limitations decisions***."[8] (Gittins Decl., Ex. D at 7.) With respect to SPD's question about whether future labeling changes were subject to the same criteria as a change under an SE without limitations, FDA said: "No, the same criteria do not apply. Following a SE with limitations decision, sponsors must submit a new 510(k) in order to make changes to the

[8] Indeed, after several drafts of proposed labeling had passed between SPD and the FDA, FDA rejected certain SPD proposals and said: "This is our final decision regarding presentation of Weeks Estimator performance in your labeling. Please note that FDA makes final determinations of labeling requirements for SE with limitations decisions." (Gittins Decl. Ex. G.)

limitation labeling (and relevant material)." (*Id.*) Moreover, the post-clearance inquiry C&D instigated eliminates any doubt on this point: FDA mandated that minor deviations from the approved packaging be changed. FDA could not be clearer that its action represents a floor ***and*** a ceiling when it comes to the labeling of this product.[9]

Finally, in rejecting the Government's position, the Court distinguished *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) because there, the Court barred a private lawsuit "because it directly conflicted with [a federal] agency's policy choice . . . ." *Id.* at 2241. In contrast, "FDA has not made a policy judgment that is inconsistent with POM's Lanham Act suit. . . . This is not a case where a lawsuit is undermining an agency judgment . . . ." *Id.*

Here, of course, FDA ***has*** made a policy judgment ***directly*** contradictory to C&D's claims: that the Product packaging will not mislead consumers about what the Product does. Any judgment in C&D's favor will necessarily undermine that agency determination, made pursuant to express authority under the FDCA.

In sum, *Pom Wonderful* did not erode the principle that a Lanham Act claim that directly conflicts with FDA's determinations are barred. Rather, it reaffirmed that principle in the explicit distinctions it drew.

III. C&D's False Advertising Claims Are Precluded Because They Seek To Attack The FDA's Clearance Of The Weeks Estimator.

Discovery has shown that C&D's Lanham Act claim is not only a direct assault on the FDA conclusion that the marketing limitations it imposed are sufficient to prevent consumers from being misled to their detriment, but that C&D's challenge is ultimately disconnected from

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[9] The FDA's prohibition on placing the LMP/ovulation conversion chart on the outside of the box is an example of this. The FDA mandated that the chart be included in the packaging, but forbid SPD from placing it on the outside of the box. Thus the inclusion mandate is a "floor," and the prohibition on adding it to the outside of the box is a "ceiling."

any specific advertising and aimed at the Product itself. That is, C&D is contending that the Weeks Estimator cannot be truthfully marketed at all. While C&D has sometimes pointed to certain elements of the advertising as misleading, its challenge is not limited to those elements. Moreover, its experts have directed their criticisms not to how the Product is specifically marketed but to the fact that, in C&D's view, it uses an illegitimate reference point – ovulation – for estimating how many weeks a woman has been pregnant. In short, C&D is asking this court to overturn the FDA's clearance entirely because, in C&D's view, the Product is inherently misleading. This position directly conflicts with FDA's exclusive statutory authority. 21 U.S.C § 301 *et seq.*

A. C&D's Deposition Testimony Made Clear That It Is Not Confining Its Allegations Of Falsity To Particular Elements Of the Advertising.

In the course of her examination on the subject of the advertising C&D contends is false or misleading, C&D's Rule 30(b)(6) witness Stacey Feldman made clear that the company is not confining its challenge to particular advertising elements. Indeed, it is clear that the company's objection stems from the use of ovulation as the starting point for an estimate of weeks ***at all.***

When asked what it would take in the way of modifying the packaging to prevent it from conveying a false message, Ms. Feldman initially said "I can't answer that." Pressed, she volunteered: "I don't know for sure, but the name of the product, Pregnancy Test with Weeks Estimator, is a misleading false name, ***so the whole proposition would need to be reworked***." (Knowles Decl., ¶ 4, Ex. C ["Feldman Dep."], 46:21-47:18.) Indeed, when asked about C&D's contention that the presence of the word "weeks" in the display window depicted on the launch packaging was deceptive, Ms. Feldman testified that ***any*** expression of a numerical estimate

based on ovulation rather than LMP "is wrong." ([Feldman Dep. at 51:8 – 52:13].[10]

Similarly, Ms. Feldman testified that the Weeks Estimator television commercial is false and misleading because, among other things, it fails to state in the last three frames that the estimate of weeks is based on ovulation. (Feldman Dep., 71:21-74:2.) When asked whether the disclosures elsewhere in the commercial – disclosures that ***do*** state that the estimate of weeks is based on ovulation – prevent the commercial from being misleading to consumers, Ms. Feldman responded: "I don't think a consumer would understand that." (Feldman Dep., 74:3-8; 76:15-25.) This is in line with Mr. Fedlman's declaration, submitted in connection with C&D's preliminary injunction motion, in which she opines that women generally would not be interested in a pregnancy test that estimates when they last ovulated. (Dkt. 22, ¶ 26.) That is, C&D's position is that this is simply meaningless information.

B. C&D's Experts Opined That The Product Would Be Misleading Regardless Of How The Product Is Marketed.

Both of C&D's survey experts, Dr. Bruce Isaacson, and Hal Poret, based their surveys on the assumption that ***any*** suggestion that the Product estimates "Weeks Pregnant" is of necessity incurably inconsistent with "weeks since ovulation," and the Product can likely therefore never be lawfully marketed.

Expert surveys of this sort virtually always evaluate two groups of consumers: one that is exposed to the advertisement under scrutiny and one that is exposed to a "control" advertisement. The purpose of the control advertisement is to account for (i.e., "control for") factors that are not being measured by the survey, such as preexisting beliefs, elements of the advertisement not considered deceptive or other "noise." *SmithKline Beecham Consumer Healthcare, L.P. v.*

[10] This is consistent with C&D's position that the current package, which prominently displays a banner proclaiming that the Product is the "Only Test That Estimates Weeks Since Ovulation," is nevertheless deceptive. (Dkt. 140, p. 21-23.)

Johnson & Johnson-Merck Consumer Pharm. Co., No. 01 CIV. 2775 (DAB), 2001 WL 588846, at *12 (S.D.N.Y. June 1, 2001) aff'd, 19 F. App'x 17 (2d Cir. 2001).

Dr. Isaacson has acknowledged in his report that "The control is an item that is as similar as possible to the original stimulus, but removes the objectionable elements." (Knowles Dec., ¶ 5, Ex. D [Isaacson Dep., Ex. 6 at 1].) Dr. Isaacson's choice of "control" for his survey illuminates the issue of what C&D is contending "objectionable" here: he used a commercial for an ***entirely different product – one that does not have a Weeks Estimator or any other dating feature.*** Dr. Isaacson was candid in explaining why he chose a control that advertised a pregnancy test without a dating feature: "[b]ecause I believe that my control was the appropriate approach, which is we still have – we have an objectionable element, and that objectionable element is the providing of – of a Weeks – of a product called 'Weeks Estimator' in conjunction with 'pregnancy test.' And so my commercial – the – ***the control commercial that I used removes that objectionable element***, and so I think that's an important baseline for the research." (Knowles Dec., ¶ 6, Ex. E [Isaacson Dep.] 83:10-19.) In other words, the "objectionable element" is not the advertising but the Weeks Estimator feature itself.

Similarly, C&D's expert reproductive endocrinologist, Dr. Pasquale Patrizo, was very clear in his deposition that he believes there is no way to safely market the Product. Dr. Patrizio was asked: "Is it the case in your opinion that there is a risk of the misuse of this product regardless of what disclosures are made about it? A. There is a risk, yes, of using -- this product being – producing misleading, giving misleading information because when you read one to two, two to three, and you think that you are one to two, three to three weeks pregnant, that's not the same way that the doctors date a pregnancy. And that can cause misleading – misleading information." (Knowles Decl., ¶ 7, Ex. F [Patrizio Dep.] 243:16-25; 244:3-244:9 ("Q. So do you agree that this risk, that is, the risk of the misuse of the product to monitor pregnancy or the risk

that somehow someone would use the result to delay going to the doctor, cannot be totally eliminated no matter what the advertising is? A. Okay. Q. You agree with that?"] Indeed, he testified that the Weeks Estimator "***probably should not be on the market***." (*Id.* 251:12-20.)

C. C&D's Claim Should Be Dismissed As An Effort To Revoke The FDA's Clearance Of The Product.

Under the FDCA, the FDA has virtually exclusive authority to regulate medical devices. 21 U.S.C § 301 *et seq*; *Delaney v. Stryker Orthopaedics*, No. CIV.A. 08-03210DMC, 2009 WL 564243, at *2 (D.N.J. Mar. 5, 2009). The FDA is charged with investigating potential violations, 21 U.S.C §372, and has a number of enforcement powers. *See* 21 U.S.C. §§332-334; 21 C.F.R. § 810.10 *et seq.* In addition, citizens may petition the FDA to take action. 21 C.F.R. §§10.25(a), 10.30. Under section 337 of the FDCA, however, enforcement power resides *exclusively* with the FDA and the U.S. Department of Justice. There is no private right of action to enforce the FDCA. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990).

Against this background, C&D's frontal assault on the Product itself is clearly in direct conflict with exclusive agency authority. In clearing a pregnancy test with a dating feature based on ovulation for sale in the U.S., the FDA authoritatively rejected C&D's position that such a Product is inherently misleading. Under the cases cited above, such a claim must be dismissed. *See also Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014) (rejecting breach of express warranty claim that urged that Metoclopramide was unreasonably dangerous such that no warnings would have been sufficient, holding that such a challenge conflicts with the FDA's exclusive authority to approve drugs and drug labels).

CONCLUSION

For the foregoing reasons, C&D's false advertising claims under the Lanham Act and related state law should be dismissed as precluded by the FDCA.

DATED: February 3, 2015

Respectfully submitted,

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